

REMARKS

Claim 64 has been canceled without prejudice or disclaimer. Therefore, claims 62, 63, and 65-84 are pending in the present application and at issue. Claims 65, 72, 73, and 75-80 have been amended to address the indefiniteness rejection.

It is respectfully submitted that the present amendment presents no new issues or new matter and places this case in condition for allowance. Reconsideration of the application in view of the above amendments and the following remarks is requested.

I. The Rejection of Claims 72-74 under 35 U.S.C. 112

Claims 72-74 are rejected under 35 U.S.C. 112 as being indefinite. Specifically, the Office objected to the phrase "one or more of nucleotides 76-1455 of SEQ ID NO: 1."

Claims 72 and 73 have been amended as suggested by the Examiner. Applicants, therefore, submit that this rejection has been overcome.

II. The Rejection of Claims 75-79 under 35 U.S.C. 112

Claims 72-74 are rejected under 35 U.S.C. 112 as being indefinite for depending from a canceled claim.

Claims 75-79 have been amended to depend from a pending claim. Applicants, therefore, submit that this rejection has been overcome.

III. The Rejection of Claims 62-67 and 72-74 under 35 U.S.C. 112

Claims 62-67 are rejected under 35 U.S.C. 112 § 112, first paragraph, "because the specification, while being enabling for a beta-1,4-endoglucanase enzyme with SEQ ID NO: 2 or amino acids 1-456 or 1-617 of SEQ ID NO: 2..., does not reasonably provide enablement for any such enzyme that has 85%, 90%, 95% or 98% sequence identity with amino acids 1-456 or 1-617 of SEQ ID NO: 2." This rejection is respectfully traversed.

It is well settled that "[t]he first paragraph of section 112 requires nothing more than objective enablement. How such a teaching is set forth, either by the use of illustrative examples or by broad terminology, is of no importance." *In re Marzocchi*, 169 USPQ 367, 369 (CCPA 1971). Moreover, "a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first paragraph of section 112 unless there is reason to doubt

the objective truth of the statements contained therein which must be relied on for enabling support." *In re Marzocchi*, 169 USPQ at 369.

"The determination of what constitutes undue experimentation in a given case requires the application of a standard of reasonableness, having due regard for the nature of the invention and the state of the art ... The test is not quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the invention claimed ..." *Ex parte Jackson*, 217 U.S.P.Q. 804 (Bd. Pat. App. 1982).

It is also well settled that an assertion by the Patent Office that the enabling disclosure is not commensurate in scope with the protection sought must be supported by evidence or reasoning substantiating the doubts so expressed. *In re Dinh-Nguyen*, 181 U.S.P.Q. 46 (C.C.P.A. 1974). See also *U.S. v. Telectronics*, 8 U.S.P.Q.2d 1217 (Fed. Cir. 1988); *In re Bowen*, 181 U.S.P.Q. 48 (C.C.P.A. 1974); *Ex parte Hitzeman*, 9 U.S.P.Q.2d 1821 (BPAI 1988).

Moreover, in the absence of any evidence or apparent reason why compounds do not possess the disclosed utility, the allegation of utility in the specification must be accepted as correct. *In re Kamal*, 158 U.S.P.Q. 320 (C.C.P.A. 1968). See also *In re Stark*, 172 U.S.P.Q. 402, 406 n. 4 (C.C.P.A. 1972) (the burden is upon the Patent Office to set forth reasonable grounds in support of its contention that a claim reads on inoperable subject matter).

The claimed invention relates to enzymes exhibiting beta-1,4-endoglucanase activity (EC 3.2.1.4), which (a) has a temperature optimum of 65°C measured at a pH of 7.5 and (b)(i) has an amino acid sequence that is at least 90% identical to amino acids 1-456 or 1-617 of SEQ ID NO: 2 wherein identity is determined by GAP provided in the GCG program package using a GAP creation penalty of 3.0 and GAP extension penalty of 0.1 or (ii) is encoded by a DNA sequence that hybridizes to nucleotides 76-1455 of SEQ ID NO: 1 under high stringency conditions, wherein the high stringency conditions are defined as hybridization in 5xSSC at 45°C and washing in 2xSSC at 70°C.

The claimed enzymes are structurally similar because they have an amino acid sequence that is at least 90% identical with amino acids 1-456 or 1-617 of SEQ ID NO: 2 or are encoded by a DNA sequence which hybridizes under high stringency conditions with nucleotides 76-1455 of SEQ ID NO: 1. One of ordinary skill in the art would, therefore, expect that the claimed nucleic acids encoding polypeptides have beta-1,4-endoglucanase activity.

Furthermore, the specification contains an extensive disclosure of techniques which are well known in the art and indeed routine for persons of ordinary skill in the art for identifying other enzymes of the present invention. For example, Applicants describe standard methods for preparing and probing DNA libraries for isolating nucleic acids encoding the enzymes of the present invention. In addition, the specification describes the use of probes and hybridization techniques for identifying nucleic acid sequences encoding enzymes of the present invention. These techniques are routine for persons of ordinary skill in the art. Thus, it is well within the skill of the art to isolate and identify the claimed enzymes using these techniques.

The Office alleges that "it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims...." This contention may have been true many years ago, however, it is certainly not the case as of the effective filing date of this application. As of June 1999, persons of ordinary skill in the art were able to routinely produce thousands of variants of SEQ ID NO: 2 through mutagenesis and other techniques in a short period of time. See, for example, Michael Lamsa, Nils Buchberg Jensen, and Steen Krogsgaard, *Screen Automation and Robotics*, in *Enzyme Functionality: Design, Engineering, and Screening*, A. Svendsen, editor, Marcel Dekker, 2003. Furthermore, at page 13, line 21 to page 14, line 2, the specification discloses how one of ordinary skill in the art could identify essential amino acids in the sequence of SEQ ID NO: 2. Therefore, one skilled in the art can predict which modifications, if any, would result in a loss of the desired activity/utility.

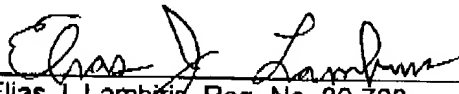
For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. § 112. Applicants respectfully request reconsideration and withdrawal of the rejection.

IV. Conclusion

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

Respectfully submitted,

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Elias J. Lambiris, Reg. No. 33,728
Novozymes North America, Inc.
500 Fifth Avenue, Suite 1600
New York, NY 10110
(212) 840-0097